GUIDELINES

Guidelines for Clinicians: The Consent Process for SARS-CoV RT-PCR and EIA Testing at CDC and Public Health Laboratories

Key messages

- A consent form is recommended when submitting specimens for SARS reverse transcription polymerase chain reaction (RT-PCR) or enzyme immunoassay (EIA) testing.
- Due to important public health concerns, if SARS testing is indicated, specimens will be tested even if a consent form is NOT received.
- A patient information sheet, informing patients about the tests and requesting permission for long term storage of their specimen remainders, will be sent to the physician with the patients test results. Physicians should provide this document to their patients.

CDC has distributed a SARS-CoV RT-PCR assay under an FDA investigational device exemption (IDE) and an enzyme immunoassay (EIA) assay to state and local public health laboratories to test specimens for SARS-CoV. These tests are used for evaluating persons suspected of having SARS-CoV infection. The RT-PCR assay is used to test for SARS-CoV viral RNA in respiratory samples, stool, plasma or serum. The EIA test is used to detect SARS-CoV antibodies in blood or serum specimens. A signed consent form is recommended to perform the RT-PCR and EIA tests because they have not been licensed by FDA and the RT-PCR test is being used under an FDA-approved IDE. In addition, a signed consent form is required to store specimen remainders for future investigations.

Health care providers desiring to submit specimens for SARS-CoV RT-PCR or EIA testing should follow these steps:

1. **Consult your state or local health department** to determine if SARS testing is indicated.
2. **Seek informed consent** from the patient for this testing.
   a. The RT-PCR consent form can be found at: http://www.cdc.gov/ncidod/sars/lab/rtpcr/consent.htm
   b. The EIA consent form can be found at: http://www.cdc.gov/ncidod/sars/lab/eia/consent.htm
3. **Collect specimens** for testing - Guidelines for specimen collection can be found at: http://www.cdc.gov/ncidod/sars/specimen_collection_sars2.htm
4. **Submit specimens** with signed consent form and completed specimen submission form to your state or local public health laboratory for testing.

Specimens will be tested at the reference public health laboratory. Final results will be reported to you through the state or local public health department. Information for interpreting these test results can be found at: http://www.cdc.gov/ncidod/sars/clinicians.htm.

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5. **Deliver test results** to the patient. If a signed consent form is not received prior to SARS testing, provide a patient information sheet/consent for long term specimen storage to the patient along with their test results. Specimen remainders stored long term may be used for future investigations.
   a. The RT-PCR patient information sheet/consent for long term specimen storage can be found at: http://www.cdc.gov/ncidod/sars/lab/rtpcr/participant.htm
   b. The EIA patient information sheet/consent for long term specimen storage can be found at: http://www.cdc.gov/ncidod/sars/lab/eia/participant.htm
6. **If appropriate, fax the completed patient information sheet** to your state or local public health department.

Frequently Asked Questions

Where do I get information on how to report a suspect SARS case and how to submit specimens for SARS testing?
This information is available through your state or local health department. Contact information is available at http://www.cdc.gov/other.htm#states.

Why is a signed informed consent recommended for SARS testing?
A signed consent form is recommended because the RT-PCR and EIA tests have not been licensed by FDA and are being used under an FDA-approved investigational device exemption (IDE). In addition, consent is required to store specimen remainders for future investigations.

Why are there two different consent forms, one for RT-PCR and one for EIA?
Because of differing IRB review requirements, two separate protocols were reviewed and approved by CDC IRB.

What happens if I submit specimens for testing without a signed consent form?
Because of the potentially serious public health concerns associated with SARS-CoV transmission, specimens that are received by a state or local public health laboratory without a signed consent form will still be tested.

What is the patient information sheet and when do I use it?
The patient information sheet/consent for long term specimen storage will be sent to physicians along with the patient's test results. Physicians should provide this document to their patient. It explains to the patient why SARS testing was performed on their specimens, what the results mean, and asks the patient for permission to store their specimen remainders for future investigations.